

## **BISMUTH- bismuth subsalicylate tablet**

### **Allegiant Health**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Drug Facts**

#### **Active ingredient**

Bismuth subsalicylate 262 mg (each tablet contains 102 mg salicylate)

#### **Purpose**

Antidiarrheal/Antacid

#### **Uses**

- relieves
- travelers' diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink including:
- heartburn
- indigestion
- nausea
- gas
- belching
- fullness

#### **Warnings**

##### **Reye's syndrome**

Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

##### **Allergy alert**

Contains salicylate. **Do not take if you are** allergic to salicylates (including aspirin) taking other salicylate products

##### **Do not use if you have**

- an ulcer
- a bleeding problem
- bloody or black stool

##### **Ask a doctor before use if you have**

- fever
- mucus in the stool

##### **Ask a doctor or pharmacist before use if you**

are taking any drug for

- anticoagulation (thinning the blood)
- diabetes
- gout
- arthritis

**Stop use and ask a doctor if**

- symptoms get worse or last more than 2 days
- ringing in the ears or loss of hearing occurs n diarrhea lasts more than 2 days

**When using this product**

a temporary, but harmless, darkening of the stool and/or tongue may occur

**If pregnant or breast-feeding**

ask a health professional before use.

**Keep Out of Reach of Children**

In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) right away.

**Directions**

- chew or dissolve in mouth
- **Adults and children over 12 years** : 2 tablets every ½ to 1 hour or 4 tablets every hour as needed
- do not exceed 16 tablets in 24 hours
- use until diarrhea stops but no more than 2 days
- **Children under 12 years of age:** ask a doctor
- drink plenty of clear fluids to prevent dehydration caused by diarrhea

**Inactive Ingredients**

acacia gum, aspartame, calcium carbonate, D&C red #27 aluminum lake, dextrates, magnesium stearate, maltodextrin, microcrystalline cellulose, peppermint flavor, silicon dioxide

**Package/Label Principal Display Panel**

HealthA2Z® **BISMUTH**

HealthA2Z®  
Compare to Pepto-Bismol® Active Ingredient\*

**BISMUTH**  
BISMUTH SUBSALICYLATE

**262 mg**

Sugar Free - Very Low Sodium



**Soothing Relief for:**

- Upset Stomach
- Indigestion
- Diarrhea
- Heartburn
- Nausea

**30** Flavored Chewable Tablets



**BISMUTH**

HealthA2Z®

**Drug Facts**

**Active Ingredient (in each chewable tablet)**  
Bismuth subsalicylate 262mg (102mg salicylate per tablet)..... Antidiarrheal/Antacid **Purpose**

**Uses** ■ relieves ■ travelers' diarrhea ■ diarrhea  
■ upset stomach due to overindulgence in food and drink including:  
■ heartburn ■ indigestion ■ nausea ■ gas ■ belching ■ fullness

**Warnings**  
**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.  
**Allergy alert:** Contains salicylate. **Do not take if you are** ■ allergic to salicylates (including aspirin) ■ taking other salicylate products.  
**Do not use if you have** ■ an ulcer ■ a bleeding problem ■ bloody or black stool  
**Ask a doctor before use if you have** ■ fever ■ mucus in the stool  
**Ask a doctor or pharmacist before use if you are taking a drug for**  
■ anticoagulation (thinning of the blood) ■ diabetes ■ gout ■ arthritis  
**Stop use and ask a doctor if** ■ symptoms get worse or last more than 2 days  
■ ringing in the ears or loss of hearing occurs ■ diarrhea lasts more than 2 days  
**When using this product** a temporary but harmless darkening of the stool and/or tongue may occur.  
**If pregnant or breast-feeding,** ask a health professional before use.  
**Keep out of reach of children.** In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**Directions**  
■ chew or dissolve in mouth  
■ Adults and children over 12 years : 2 tablets every ½ to 1 hour or 4 tablets every hour as needed  
■ do not exceed 16 tablets in 24 hours  
■ use until diarrhea stops but no more than 2 days  
■ Children under 12 years of age: ask a doctor  
■ Drink plenty of clear fluids to prevent dehydration caused by diarrhea

**Other information** ■ **Phenylketonurics:** contains phenylalanine 1.1mg per tablet  
Calcium content per tablet: 73mg ■ save carton for full directions and warnings ■ store at room temperature 15°–30°C (59°–86°F) ■ do not use if cellophane unit is torn

**Inactive ingredients:** acacia gum, aspartame, calcium carbonate, D&C red #27 aluminum lake, dextrates, magnesium stearate, maltodextrin, microcrystalline cellulose, peppermint flavor, silicon dioxide

\*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Pepto-Bismol®.

**Manufactured by: Allegiant Health** LB0310 R0118  
Deer Park, NY 11729



Bismuth subsalicylate 262mg

## BISMUTH

bismuth subsalicylate tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-046
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118YE)	BISMUTH SUBSALICYLATE	262 mg

### Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
DEXTRATES (UNII: G263M44RU)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ACACIA (UNII: 5C5403N26O)	

MALTODEXTRIN (UNII: 7CVR7L4A2D)

PEPPERMINT (UNII: V95R5KMY2B)

### Product Characteristics

<b>Color</b>	PINK	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	RH046
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-046-69	12 in 1 CELLO PACK; Type 0: Not a Combination Product	12/23/2014	
2	NDC:69168-046-88	30 in 1 CELLO PACK; Type 0: Not a Combination Product	12/23/2014	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	12/23/2014	

**Labeler** - Allegiant Health (079501930)

Revised: 11/2018

Allegiant Health